Patent

Decket No. BRA4.PAU.05

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Raphael C. Wong

Examiner:

Alexander, Lyle

Serial No.:

09/840,566

Art Unit:

1743

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Title:

LATERAL FLOW CONTACT TEST

APPARATUS

RULE 132 DECLARATION OF RAPHAEL WONG

- 1. I am the inventor of the above-identified U.S. patent application (the "Application") and the President of Branan Medical Corporation. This declaration is made on personal knowledge, and I am competent to testify to the matters stated herein.
- 2. Reagent compositions that detect adulterants in urine, for example, cannot be immobilized on a strip in the way that can be accomplished with antibodies or antigens in a conventional immunoassay. Therefore, an adulterant detecting reagent composition that is disposed on an absorbent carrier will tend to move along the carrier in the same direction as that of the wicking fluid.
- 3. By providing a separate adulterant pad that contains the adulterant detecting reagent composition and that is not integral with the absorbent carrier which initially receives the fluid, a major benefit resulted that would not be expected had the adulterant pad been formed integrally with the absorbent carrier.
- 4. In particular, employing a separate adulterant that is in fluid communication with the absorbent carrier, but is a separate piece from the carrier, the

color change from the reagent composition detecting the presence of an adulterant is more localized.

- 5. Furthermore, though some forward movement of the color in the adulteration pad may occur, the result is far less severe than if the reagent composition was merely disposed at one end of an elongate absorbent strip, in which case the liquid action would force the color to the distal tip of the absorbent strip.
- 6. To the best of my knowledge, part of this unexpected benefit appears to result from the combination of a separate fluid absorbent carrier that extends above and overlaps a portion of the separate adulteration pad that includes the reagent composition. As a result, a downward liquid action is caused by fluid flowing from the upper absorbent carrier to the lower adulteration pad. This downward liquid action appears to slow down the forward liquid movement which might otherwise force all the color from the reagent composition to a distal end of the adulterant pad.
- 7. Instead, the result is an adulterant pad where the color change is clearly visible when a target adulterant is detected. In particular, the color change is not forced into a thin line at a distal end of the adulterant pad which, according to the best of my knowledge, would occur if the reagent composition were not disposed on a separate adulteration pad that is overlapped by a separate absorbent carrier.
- 8. I understand that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001), and further declare that all statements made of my own knowledge are true and that all statements made on the information and belief are believed to be true. I hereby declare further under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: <u>April 192008</u>

By:

Raphael Wong